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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

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EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/692,634	RENNIE ET AL.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,20-22,26,27,54 and 57-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,20-22,26,27,54 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are pending.

In view of applicants arguments in the Appeal Brief Filed on July 29, 2009, the finality of the previous Office action dated November 13, 2008 has been withdrawn.

Priority

This application is a continuation in part of application 09/421,131 dated October 19, 1999.

Action Summary

The rejection of claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 under 35 U.S.C. 103(a) as being unpatentable over Diehl (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927) is withdrawn.

However, upon further reconsideration the following rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl (EP0505374B1) of record and Tulin-Silver (U.S. Patent 5,508,282) in view of Makino et al. (US Patent No. 4789667) of record and in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927), of record and in further view of "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Version 1996 (77th Edition), David R. Lide, ed., Taylor and Francis, Boca Raton, FL. pp.3-15 and 3-173) of record.

Diehl teaches, on page 2, a pharmacological composition for treatment of the common cold by spraying said composition into the oral cavity (with mucosal absorption of the composition posited as the means of administration). The composition comprises vitamin C (ascorbic acid) and a non-toxic zinc salt. In example I Table 1 Diehl teaches a suitable zinc-vitamin C composition that includes pharmaceutical grade water, ascorbic

acid (1.64% by weight), sodium bicarbonate (0.14% by weight), glycerine, potassium sorbate, EDTA, zinc gluconate (1.09% by weight), L-lysine, glycine, fruit juice, sucrose, magnasweet, tween-80, trace bioflavonoids, orange flavoring and peppermint oil.

Diehl does not teach direct spraying of the composition into the nasal turbinates, or the use of pyroglutamic acid in the composition.

Tulin-Silver teaches a composition comprising of Vitamin C (ascorbic acid) from about 15 mg to about 300 mg and zinc in the amount of 0.50 mg (column 4, lines 15-35). Tulin-Silver teach that such composition is for the treatment of relieving and shortening the duration of inflamed nasal membrane turbinates (which include allergic, infectious, vasomotor, atrophic, hormonally-induced vasomotor instability and non-allergic causes); nasal and sinus congestion (such as that in sinus headaches associated with acute or chronic sinusitis), acute upper respiratory infections (common colds), acute or chronic allergy flare-ups of the nose, and/or acute or chronic non-allergic rhinosinusitis (column 1, lines 1-24). Tulin-Silver's pilot study demonstrated that the nasal spray formulations shortened the duration of common cold symptoms from seven days to three days (column 4, lines 53-55).

Makino et al. teach, in the abstract, a pharmaceutical composition for external use with enhanced penetration of a pharmacologically active agent through the skin or mucosa, said composition comprising a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester. In col. 3 lines 55-65, Makino et al. teach that in US Patent No. 4434159 a drug which is substantially unabsorbable through the

mucosa of the rectum is made absorbable through the rectal mucosa by co-administration with a penetration enhancer (pyroglutamic acid or a salt thereof). Makino et al. teach, in col. 12 lines 17-40, that the compositions contain the penetration enhancer in an amount of from 0.2-25% by weight, preferably 0.5-12% by weight based on the total weight of the composition. Further the mucosa may be that of the rectum, oral cavity, nasal cavity or vagina. Makino et al. teach, in col. 14 line 1 to col. 15 (table 2 comparison 16 and 17), ointments prepared from 1 part of nifedipine, 10 parts L-pyroglutamic acid (comparison 1) or 10 parts DL-pyroglutamic acid (comparison 2), 89 parts of a gel ointment base (composed of 1 part of Carbopol 934-a mucoadhesive agent as defined in the current specification page 8 lines 1-10, 12 parts of propylene glycol, 30 parts ethanol, 1 part diisopropanolamine and 56 parts water). Thus the penetration enhancer (L- pyroglutamic acid or DL-pyroglutamic acid) is present in 10% by weight, the Carbopol 934 is present in 1% by weight, and the pharmacologically active agent is present in 1% by weight.

Kuhrt et al. teach, in the abstract, that Rhinoviruses as a group are notably sensitive to inactivation in solutions with a pH of less than 5.3: On page 924, Kuhrt et al. teach that glutaric acid (one of the organic acids currently claimed) has been demonstrated as an effective virucidal agent against rhinovirus on human skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made employ the teachings of Tulin-Silver to that of Deihl to formulate a composition comprising ascorbic acid and zinc that is suitable for administration in the

nasal passages as taught by Tulin-Silver. One would have been motivated to employ nasal formulations because the nasal spray formulations shortened the duration of common cold symptoms from seven days to three days as taught by Tulin-Silver. Thus, one of ordinary skill would have a reasonable expectation of success that by employing the teachings of Tulin-Silver to that of Deihl to formulate a composition comprising ascorbic acid and zinc that is suitable for administration in the nasal passages as taught by Tulin-Silver, one would shorten the duration of the common cold.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ointment composition of Makino et al. comprising a penetration enhancer (pyroglutamic acid) and ointment base (that could be applied to mucosa of the rectum, oral cavity, nasal cavity or vagina), with the pharmacological composition of Deihl comprising ascorbic acid and zinc gluconate in order to formulate a composition for treatment of the common cold. One would be motivated to add the Makino et al. ointment compositions to the Deihl compositions in order to achieve enhanced penetration of the ascorbic acid and zinc gluconate and thus achieve a greater effectiveness against the common cold. One would be motivated to adjust the overall pH of the combined formulation to less than pH 5.3 as Kuhrt et al. has demonstrated that rhinoviruses are inactivated by acidic conditions wherein the overall pH is less than 5.3. One would further be motivated to use glutaric acid as an organic acid with the combined formulation either in conjunction with ascorbic acid or by itself in treating the common cold as Kuhrt et al. show that Glutaric acid is an effective virucide against rhinovirus (on human skin).

The examiner respectfully points out the following from MPEP 2144.06: "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

The determination of optimal viscosity, optimal pH ranges, and optimal pKa ranges are matters of routine experimentation.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

With regards to requirement of pKa being that of 3.0-5.0 of the organic acids as claimed. Examiner respectively points out that the properties of compounds are not

deemed patentable. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004),* the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Futhermore, as evidentiary data that pKa are properties of pyroglutamic acid, the "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics demonstrates that the pKa requirement of 3.0-5.0 of the organic acids as claimed are the same physical/chemical properties of the claimed organic acids (see pages 3-15, 3-173).

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642